

With respect to the Examiner's comments on the arrangement of the specification, applicant wishes to point out that the specification is arranged in the manner suggested by the Examiner although section headings have not been provided. Applicant wishes to point out that section headings are not required and requests that this suggestion of the Examiner be withdrawn. In the foreign filing of applications, it has been found that in many cases such section headings must be deleted. For that reason they have been omitted.

The reference numeral 11 will be added to Figure 1 of the drawings as suggested by the Examiner. Upon allowance of the claims a new formal drawing showing this reference number will be submitted.

The claims of record have been amended to overcome the Examiner's objection to non-statutory subject matter.

With respect to the Examiner's rejection under 35 U.S.C. §112, applicant submits that these objections are unwarranted and should be withdrawn. Applicant submits that the words "in the vicinity" have a clear meaning as meaning near or close by or in an area surrounding a particular place. This is certainly apt terminology for applicant's acoustical device and the manner in which it is positioned on the face of the patient.

In dependent Claim 16, the Examiner has objected to use of the language "the first named and additional output signals". Applicant submits that this is apt language. The first named output signal is the output signal mentioned in Claim 16 and is therefore definite. The additional output signal is defined in Claim 16.

Also with respect to Claim 16, the Examiner objects to the term "substantially free". Applicant submits that this is an apt term. As the Examiner appreciates, this is not a precision world. For example, it cannot be claimed that all of the ambient noise has been removed by the electronic means disclosed. Applicant therefore submits that this language is appropriate and the objection should be withdrawn.

The Examiner has rejected Claims 1-5, 9-10 and 15-16 under 35 U.S.C. §102(a) as being anticipated by Sullivan et al. Sullivan et al. discloses a device for treating obstructed breathing. Sullivan et al. uses a nose mask 12 which completely encloses the nose and nasal passageways so that the total flow into and out of the nose is contained within the nose mask 12. A microphone 11 is positioned exterior of the nose piece but is apparently in communication with the interior of the nose piece. An electronic processor/recorder is utilized for recording signals from the microphone 11 either on a time basis or after preprogrammed processing (see col. 8, lines 45-46). The microphone 11 can be utilized

in connection with a CPAP apparatus as shown in Figure 3 to create an electric signal when snoring sounds occur. The snoring detection device 22 drives a motor speed control means to increase the speed of the electric motor 20 by analogue means to thereby increase the output pressure of the CPAP unit in response to the detection of snoring. CPAP pressure is increased until the upper airway is stabilized and snoring ceases (col. 10, lines 3-8).

The rejected claims have been amended to clearly define invention over Sullivan et al. First the claims now specify that the acoustical device is provided for receiving less than the actual air volume exhaled and inhaled by the patient. This is not true in Sullivan et al. in which the nose mask 12 receives all of the actual air volume exhaled and inhaled by the nose of the patient. Such a configuration is necessary for Sullivan et al. to supply CPAP.

Claim 1 also calls for means for providing estimated volume of air flow for processing the electrical output signal to provide a real time signal indicative of breathing of the patient. Such means is not disclosed in Sullivan et al. nor is it necessary because in Sullivan et al., it is contemplated that all of the air flow into and out of the nose of the patient will pass through the nose mask. Therefore Claim 1 clearly defines invention over Sullivan et al.

Claims 2-4 include the subject matter of Claim 1 and are patentable for the same reason as Claim 1. Claim 2 in addition calls for an ambient sensor in communication with the space but spaced away from the change sensing sensor to minimize acoustical and mechanical coupling. The claim also calls for means for supplying oxygen flow to the patient. Such a combination is not shown or suggested by Sullivan et al.

Claim 5 is also dependent on Claim 1 and is patentable for the same reason as Claim 1. It also calls for an additional sensor. As pointed out with respect to Claim 2, Sullivan et al. does not use such an additional sensor. Claims 9 and 10 are dependent on Claim 1 and are patentable for the same reason as Claim 1. Claims 9 and 10 more specifically define the applicant's acoustical device. Such a device certainly is not disclosed by Sullivan et al. In Sullivan et al. there is merely disclosed a nose mask 12 which completely controls the flow of air into and out of the nose of the patient.

Claim 10 is dependent on Claim 9 and is patentable for the same reason as Claim 9.

Claim 15 is a method claim and calls for the use of an acoustical device for receiving less than the actual air volume exhaled and inhaled by the patient and adapted to be positioned on the face of the patient. As pointed out with respect to Claim 1, in Sullivan et al. a nose mask 12 is provided which controls all of the air flow into and out of the nose of the patient. Claim 15 also goes on to call for

providing an estimated volume of air flow to provide a real-time indication of actual respiratory flow from the patient. Such a method certainly is not disclosed or suggested by Sullivan et al.

Claim 16 is dependent on Claim 15 and calls for the step of sensing respiratory and ambient noise in the vicinity of the face of the patient. Such means is not disclosed by Sullivan et al.

The Examiner has rejected Claims 6-8 and 17-20 under 35 U.S.C. §103 as being unpatentable over Sullivan et al. First it should be pointed out that Claim 6 is now dependent upon Claim 5 and is patentable for the same reason as Claim 5. Sullivan et al. merely discloses a microphone and no specifics as to what is detected to ascertain whether or not snoring is taking place. There certainly is no indication that respiratory sound intensity is being measured or is being measured in the form of dB_A. Similarly with respect to Claim 8, there is no disclosure in Sullivan et al. of displaying the sound intensity at predetermined time intervals.

Similarly the subject matter of method Claims 17-20 certain is not disclosed or suggested by Sullivan et al. The Examiner merely states that Sullivan et al. discloses generating a signal after a snore or a sequence of snores is detected (col. 9, lines 58-59). This certainly does not suggest a predetermined time interval. In fact the statement of Sullivan et al. directed to the contrary and merely states that the time is indefinite and can extend for the entire time that the patient is sleeping without a signal being generated.

It is therefore respectfully submitted that Claim 6-8 and 17-20 are patentable.

The Examiner next rejected Claims 11-14 under 35 U.S.C. §103(a) as being unpatentable over Sullivan et al. and further in view of Derrick. Derrick 5,046,491 discloses an apparatus and method for respired gas collection and analysis. It includes a respired gas collection and transport apparatus 10 mounted on the face of the patient which includes a nasal respired gas cannula member 18 and an oral gas hood 42. Expired gases are captured and analyzed in a gas analysis apparatus as shown in Figure 3. Certainly there is no teaching in Derrick of providing an apparatus for breath monitoring to provide a real-time indication of breathing of the patient and for recognizing disordered breathing patterns. With respect to the Examiner's argument that it would have been obvious to combine the teaching of Derrick with that of Sullivan et al. to provide the apparatus called for in Claim 11-14, it should be pointed out that in Sullivan et al. it is necessary that all of the gases flowing into and out of the nose of the patient be collected. Thus the teaching of Derrick is inapt because it applies to a face piece in which there is no attempt to collect all of the exhaled gases. Thus Derrick utilized a very different facial apparatus than that disclosed by Sullivan et al. and combining the teaching of the two references is

unwarranted. In addition it should be pointed out that Claims 11-14 depend from claims which in and of themselves are patentable. It is therefore respectfully submitted that they are also patentable. In addition the specific construction called for in Claims 11-14 is not shown by Derrick.

With respect to Claim 21, it now calls for the step of displaying disordered breathing events. Although the use of displays may be old, the use of means to display disordered breathing events certainly is not suggested by Raviv et al.

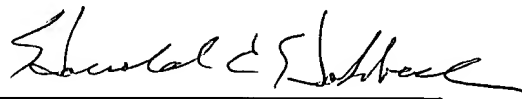
New method Claims 22-25 have been added, all of which include the subject matter of Claim 15 and are patentable for the same reason as Claim 15. They define additional steps which are not shown or suggested by any of the references relied upon by the Examiner. It is therefore respectfully submitted that these Claims 22-25 are also patentable.

New apparatus Claims 26-28 are being submitted to more clearly define applicant's invention over the references relied upon by the Examiner. As pointed out with respect to Claim 1, Claim 26 also includes means for providing the estimated volume of air flow. Such means certainly is not suggested or disclosed by any of the references relied upon by the Examiner in connection with a breath monitoring apparatus. Claims 27 and 28 include the subject matter of Claim 26 and are patentable for the same reason as Claim 26. In addition they define additional features of applicant's invention which are not shown or suggested by the references relied upon by the Examiner.

In view of the foregoing, it is respectfully submitted that the claims of record are allowable and that the application should be passed to issue.

Respectfully submitted,

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